Rational Pharmaceutical Management Plus
Technical Visit to Kenya for Tuberculosis Patient Packs: Trip Report
April 25 - May 1, 2004

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About RPM Plus

The Rational Pharmaceutical Management Plus (RPM Plus) Program, funded by the U.S. Agency for International Development (cooperative agreement HRN-A-00-00-00016-00), works in more than 20 developing countries to provide technical assistance to strengthen drug and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

Abstract

Kenya is switching to patient packs to improve procurement, distribution and use of TB medicines. The change is expected to improve treatment outcomes of patients and standardize treatment among the various segments of the population. The technical assistance provided to Kenya during this visit should serve as a model for other TB programs wishing to do the same since a comprehensive plan and various tools are provided.

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Key Words

Tuberculosis, Kenya, patient kits, patient packs, quantification, phase in

Contents

Acronyms

DELIVER	USAID project
GDF	Global TB Drug Facility
KEMSA	Kenya Medical Supplies Agency: The central medicines procurement, supplies and warehousing agency for Kenya; a parastatal
NLTP	National Leprosy and TB Program – Kenya
USAID	United States Agency for International Development
WHO	World Health Organization

Background

Management Sciences for Health (MSH) through the Rational Pharmaceutical Management Plus Program (RPM Plus) and as partner with the Global TB Drug Facility (GDF) participates in country visits to determine if recipient countries of tuberculosis (TB) medicines are following good TB pharmaceutical management practices as established in letters of agreement between the GDF and recipient countries. RPM Plus participated in such a visit to Kenya in February 2004. Although the findings were generally good for continuing GDF support, a strong need was identified by the team in providing technical assistance to the National Leprosy and TB Program (NLTP) in their planned switchover to patient packs.

A patient pack is a box containing all the medicines needed for a complete course of treatment. Thus, all four drugs for the two month intensive phase and two drugs for the six month continuation phase are contained in a single box. A patient pack has several advantages as follows:

- prevents interruption of treatment once a patient has started treatment
- allows patients to see that all their medicines will be available at the facility when they need them
- lets patients know that treatment is not complete until all their medicines are taken
- makes quantification of drug needs by the NLTP much easier since only one product needs to be considered (one patient = one patient kit)
- facilitates ordering by the health units since only one item is handled as opposed to the five or six medicines normally handled

The NLTP placed an order for patient packs to cover a full year's needs starting in June 2004. As a result GDF and the NLTP asked RPM Plus to provide technical assistance to assure a smooth phase-out of existing separate medicines and phase-in of the patient packs.

Thomas Moore, Principal Program Associate for TB, and Hugo Vrakking, RPM Plus Senior Program Associate seconded to the GDF, visited Kenya from April 25 - May 1 to initiate the activities. Travel was funded through the RPM Plus SO5 TB budget.

Scope of Work

The scope of work was as follows:

- Visit selected facilities of the NLTP pharmaceutical supply system including health clinics where patients receive TB drugs
- Discuss current situation with the NLTP
- Elaborate a comprehensive plan and procedures for pharmaceutical management switchover including the following:
  - Conditions and storage capacity of the central and district warehouses
  - Procurement specifications to assure receipt of quality products and appropriate delivery points within the country

- Official communications to provinces and districts to announce new patient kit program
- Distribution strategy including delivery frequency consistent with storage capacity of different storerooms and warehouse
- Adaptation of management information system (e.g. forms, computer spreadsheets)
- Handling partially-used patient kits (from patients who transferred, etc)
- Training and communication strategy for all key health workers including procedures for pharmaceutical supply and patient drug treatment.
- Monitoring and evaluation strategy to document the Kenya switching-over process for later development of a viable guide that any national TB program can use
- Buffer stock and separate drugs for patients having adverse reactions
- Pilot project concept to iron out wrinkles in original plan
- Steps to phase out existing TB drugs

- Brief stakeholders and USAID on completed activities and next steps

Activities

1. Visit selected facilities of the NLTP pharmaceutical supply system including health clinics where patients receive TB drugs

   The team visited several medicine supply depots and health units as follows.

   - Machakos District depot and dispensary. There are about 50 patients currently under treatment for TB. According to the national TB program guidelines patients take home a one-week supply of drugs and return once a week for the intensive phase of 2 months; for the continuation phase patients take home a month's supply each visit. The same scheme will be followed when patient packs are phased in. There appeared to be enough room to store patient packs which will take up more space than separate drugs. Lack of secure storage cabinets and shelving were a noted problem however. When told of the planned switchover to patient packs the health workers thought it would be a great boost for the program
   - Athi River Health Centre. This health center currently treats approximately 50 patients as well. NLTP treatment policies were being followed and space for the patient packs is available. Additional secure cabinets will be necessary to facilitate storage of the packs in patient treatment rooms. Providers were very excited about the coming of the packs and thought they would enhance their work and patient response to treatment
   - Jericho Health Centre, Nairobi. The center currently treats 81 new TB cases and 21 retreatment cases (Category II patients according to WHO definition). There was plenty of storage room in patient treatment and storage rooms and all are secure areas. The center will need additional shelving and cabinets. Providers are interested in the patient packs and do not see a problem with adapting them to lighter weight patients as long as they have adequate training prior to implementation of the packs.
   - Pumwani Dispensary. Nairobi. Pumwani is a very busy urban center currently treating 140 TB patients. Providers think the patient packs are a good idea but many of the patients are refugees from Somalia and are having difficulty understanding they must take the medicines for a full eight months to be cured. This would result in a lot of partially used patient packs. Space could be a problem but the center could reorient a current room for storage purposes if needed. The center would need additional shelves and cabinets to store the patient packs
   - Langata Health Centre, Nairobi. This center is slowly becoming a district hospital because of realignment of districts by the Ministry of Health. The center currently treats 51 patients and on average 5 will transfer out leaving partially used patient packs. The providers are ready to implement the new pack system, however.
   - KEMSA central warehouse. KEMSA, currently a parastatal is likely converting to a private company in the near future but will continue to procure and distribute medicines for the Ministry of Health. KEMSA is scaling up to conduct quality control inspections and laboratory testing. KEMSA conducted the ICB to procure the NLTP patient pack. The patient pack order will arrive in May and June and KEMSA is making space for storage of the products either in their Nairobi warehouse or in additional nearby warehouses.

The USAID/DELIVER project is providing technical assistance to KEMSA for improving the distribution system of essential medicines to regional warehouses, health centers and hospitals throughout the country. TB medicines are included in this scheme and DELIVER was involved in the KEMSA/MSH discussions.

- Cosmos Limited located in Nairobi. Cosmos is the manufacturer and supplier of the NLTP patient packs. MSH and NLTP met with representatives of Cosmos to discuss additional requirements for the patient packs such as placing a booklet inside each patient pack instructing providers how to adjust the kit for TB patients of different weights, adapting the outer labels to function for dose recording while patients take their medicines throughout the course of treatment, and appropriate packing for delivery throughout Kenya by the KEMSA unit. The last leg of the distribution chain for essential medicines means a cardboard container atop a small motorcycle or bicycle and the patient packs need to accommodate this as well.
- KEMSA regional warehouse. The team was not able to visit any of the eight regional KEMSA warehouses but DELIVER described how they are functioning.

2. Discuss current situation with the NLTP

RPM Plus met with the Head of the NLTP Dr. Chakaya and his senior advisor Dr. Mansoer to discuss the current situation and findings from the site visits. RPM Plus discussed with the NLTP various criteria and options for phasing out the current separate drugs and phasing in the patient packs as follows:

- Standardizing treatment regimens so that nomadic populations receive the same regimens and drugs over the same time periods as the rest of the population; otherwise separate drugs would accumulate causing some to reach their expiry dates before being used, while the national program would have to purchase some additional separate drugs to make the combinations run out at the same time. RPM Plus prepared a spreadsheet with two options for phasing out the existing separate drugs and simultaneously phasing in the patient packs to prevent drugs from reaching their expiry dates and to avoid drugs being out of stock during the transition period. See annex 5.
- Plan to repack patient packs on a periodic basis since excess drugs will accumulate from transfers to other health facilities, patients defaulting treatment and deaths: the NLTP patient packs contain the standard quantities of drugs needed for the highest weight band, wherefore left over drugs can never be absorbed in adjusting patient packs for other patients; RPM Plus prepared a repack procedural guide so that workers will follow GMPs during the repacking operation. See annex 4.
- NLTP to work with District Health Officers to determine if a particular health center is ready to phase in the patient packs, for example providers have been trained, TB population is somewhat stationary at that health center, and patients transferring out are not a big problem.
- The patient packs to be phased in first in smaller and peripheral health centers, and gradually at TB treatment centers with high number of patients, while the patient packs might not be the best option in the large hospitals.

3. Elaborate a comprehensive plan and procedures for pharmaceutical management switchover including the following:

    - RPM Plus prepared a comprehensive plan with individual activities and steps to carryout the switchover and presented it to the NLTP. See annex 1.

4. Conditions and storage capacity of the central and district warehouses

    - RPM Plus determined that storage at the KEMSA central warehouse is not a problem. DELIVER has plans for distributing to health centers through KEMSA regional warehouses. The district depots did not seem to be problematic for storing and distributing patient packs. However in almost every case, additional shelving and cabinets will be needed in all units to accommodate the patient packs; RPM Plus and the NLTP met with the USAID mission and discussed the possibility for financial resources to provide the needed storage furniture. USAID identified money they could earmark for this purpose. The NLTP is preparing a budget to submit to USAID for this purpose.
    - Handling partially-used patient kits (from patients who transferred, etc). See annex 4 for procedure and check lists prepared by RPM Plus to carryout these procedures.
    - Training and communication strategy for all key health workers including procedures for pharmaceutical supply and patient drug treatment. NLTP to prepare a comprehensive training scheme and training materials to prepare the NLTP staff at all levels for the introduction, delivery, storage and treatment of patients with the patient packs. Special emphasis should be given to take advantage of the new possibilities the patient packs offer for improved patient education and treatment adherence.
    - RPM Plus prepared the text for booklets for the 2 types of patient packs: for Category I and Category III TB patients, on how to appropriately use the patient packs and demonstrated their usefulness to the NLTP. The manufacturer will pack the booklets with the patient packs before delivery of the order. The text of booklets is also available in the RPM Plus office.

5. Monitoring and evaluation (M and E) strategy to document the Kenya switch-over process for later development of a viable guide that any national TB program can use. RPM Plus will continue to communicate with the NLTP as the switchover takes place and collect information for developing an M and E strategy. In addition RPM Plus prepared supervisory checklists that district health officers can use to evaluate TB pharmaceutical management in health units and district depots. The checklists can be used for all essential medicines but also focus on items specific to the patient packs. See annexes 2 and 3.

6. Buffer stock and separate drugs for patients having adverse reactions. RPM Plus discussed the issue of needing separate drugs for patients having adverse reactions to the fixed dose combination products in the patient packs. A formula of 2% of the total number of patients was recommended to cover these exceptional cases. RPM Plus discussed the recommendation by WHO that separate drugs are best held at reference centers. The NLTP plans to keep separate drugs at district depots.

7. Pilot project concept to iron out wrinkles in original plan. Since the patient packs are arriving very soon containing one product (4-drug fixed dose combination) with a 24 months

shelf life it was decided to forego the pilot phase. Because of the need to phase out existing drugs, all patient packs will not be used the first year of the switchover, but will be totally consumed well before the expiry dates of the combination product according to the phase out spreadsheet prepared by MSH.

8. Steps to phase out existing TB drugs. RPM Plus prepared a spreadsheet with two options for phasing out existing drugs and simultaneously introducing the patient kits into health centers. The recommended phase out method would be to standardize treatment regimens for nomadic and non-nomadic TB populations. That way no extra separate drugs would need to be purchased, no existing separate drugs would run out of date, and no patient packs would expire. See annex for copy of spreadsheet

9. Brief stakeholders and USAID on completed activities and next steps. RPM Plus jointly with the NLTP met with USAID Mission focal point Dr. John Washonga to discuss the RPM Plus work in Kenya, the recommendations and need for additional Mission support in the form of shelving and secure cabinets and the printing of the instruction booklets for the patient packs.

In addition RPM Plus prepared a procedure for setting up an appropriate quality assurance system for TB medicines and patient packs. The procedure discusses the need for physical inspection of shipments and laboratory testing on a random or more frequent basis. Although not a responsibility of the NLTP, Dr. Chakaya agreed that he would promote setting up such a procedure with the national regulatory authorities, KEMSA and government procurement officers. See annex 7.

The NLTP asked RPM Plus to quantify medicine needs for 2005-2006 taking into account the phase in of the patient packs. See annex 6 for these calculations.

Collaborators and Partners

Dr. Jeremia Chakaya, Director of NLTP
Dr. John Mansoer, Senior advisor to NLTP
Dr. John Wasonga, USAID TB focal point
Dr Charles Kandie, Chief Executive of KEMSA
Jane Waweru, DELIVER coordinator
Michael Thuo, RPM Plus Kenya office director
Dr Wilberforce O. Wananga, Cosmos Limited
Mr. Laxman K. Varsani, Cosmos Limited
Mr. Vimal P. Patel, Cosmos Limited

Next Steps

- The NLTP will prepare a budget including depots and health centers needing shelving and secure cabinets, staff training costs and printing cost of the explanatory booklets and present to the USAID mission
- The NLTP will meet with district health officers to select the health centers where patient packs will first be used during the phase out-phase in period
- The NLTP will prepare a specific training plan eventually for all TB health providers but initially for those health centers and their supervisors where patient packs will first be implemented
- The NLTP has asked if RPM Plus will be able to return to Kenya to help with the training in July 2004; RPM Plus will discuss this possibility with the GDF and at a minimum review the training materials planned for use
- The NLTP will give the labeling specifications on the patient pack and outer containers prepared by MSH to Cosmos prior to the May and June shipments
- The NLTP will share the repacking procedural guidelines developed by MSH to DELIVER who will implement the procedures in the regional warehouses; MSH has suggested at least a quarterly repacking frequency to avoid expiry of drugs in partially used kits
- RPM Plus will be available for long distance technical assistance as needed
- Once the patient packs system has been implemented in Kenya RPM Plus will prepare a guide and disseminate to other national TB programs and share with other organizations during international, regional and country activities such as the UNION World Conference on Lung Health in October 2004.

Annex 1

National Plan for Switching to Patient Packs

The National Leprosy and TB Programme (NLTP) has decided to switch as many TB patients as possible to Patient Packs. The objectives of the switchover are to improve treatment outcomes and to standardize treatment regimens. The TB Patient Pack has enough drugs in one container for a full course of treatment for 1 patient. Intensive phase drugs are segregated from continuation phase drugs within the single TB Patient Pack. Currently TB drugs consisting of 2 and 3-drug fixed dose combination products and separate drugs in blisters and in pots are being used in the system. With the patient pack the NLTP sees the following benefits:

- *Standardized treatment:* allows health workers to select a single container which has the predetermined drugs, strengths and quantities (the TB Patient Pack) for administering to the patient versus multiple containers and dosages in various packaging configurations
- *Quantification for procurement or ordering*: improves ease of estimating drug needs whereby 1 patient = 1 patient pack, as opposed to current methods which require quantifying multiple drugs in multiple doses
- *Distribution of TB drugs:* improves ease of logistics in that 1 item is being transported versus multiple products in a variety of containers
- *Stock management and inventory control:* improves ease of managing stocks and documentation of stock movement in that 1 product is being handled versus multiple products
- *Patient adherence:* whereas drug stock-outs cause patients to lose confidence in the health system, the Patient Pack assures the TB patient that his or her drugs will be available from start to finish of treatment; also the patient feels ownership of the Patient Pack and will likely complete the full course of treatment since the patient can see how many drugs must still be taken to be cured during visits to the health centre or dispensary

The following plan was developed in collaboration with the NLTP and Management Sciences for Health's Rational Pharmaceutical Management Plus Program funded by USAID. The Plan includes a list of decisions, some options still to be considered, steps for implementing the switchover and recommendations for future consideration. The matrix from the *Operational Guide for National Tuberculosis Control Programmes on the Introduction and Use of Fixed-Dose Combination Drugs (WHO/CDS/TB/2002.308)* was used as a background for developing this plan.

Decision-making phase

Decision to make	Results	Status of activity	Remaining activities and dates to complete
Number of different TB Patient Packs to be made available	• One pack for Category I patients containing 2RHZE (150/75/400/275 mg) and 6EH (400/150 mg) in blister sheets of 10 tablets • Second pack for Category III Patients containing RHZ (150/75/400 mg) and 6EH (400/150 mg) in blister sheets of 10 tablets	Both packs have been tendered and are currently being manufactured. Expected delivery dates are May/June 2004: 60,000 packs for Category I 40,000 packs for Category III	none
Number of blisters in each TB Patient Pack	• Category I TB Patient Pack will contain: 24 blister sheets of 10 = 240 tablets of RHZE: and 36 blister sheets of 10 = 360 tablets of EH • Category III TB Patient Pack will contain: 24 blister sheets of 10 = 240 tablets of RHZ and 36 blister sheets of 10 = 360 tablets of EH	Already manufactured	none

Decision to make	Results	Status of activity	Remaining activities and dates to complete
Where will TB Patient Packs be used	• Only in health centres during the first year • Decision to not use in hospitals due to high transfer – out rate of patients • Some health centres with large numbers of patients (>100 at any time) and health centres with larger number of transfer-out patients will be excluded from using patient kits as recommended by the DTLC • Some health centres may use patient kits especially for TB patients with high expectation for defaulting (perceived ownership of TB Patient Pack)	To begin in July	None
	•	•	•
	•	•	•
Decisions to be made on changing treatment regimens for Cat III and Nomadic patients	• Cat I and Cat III to receive same treatment: same treatment pack. • Selected Nomadic population to receive same treatment as sedentary population • Result: NLTP has only 2 treatment regimens (and patient packs): 1 for new cases, 1 for re-treatment cases	• Decision in principle: to be finalised	• Before June 2004, to be included in next tender specifications

Decision to make	Results	Status of activity	Remaining activities and dates to complete
Special markings needed on the TB Patient Packs	• Self adhesive label on end where patient name, TB register number and registration date can to be written. • Self adhesive sticker on inside lid of pack where the following are written: weight of patient, number of tablets per to be taken in one dose and spaces to tick when each dose is taken by the patient: Control Card	• Requirements discussed with the manufacturer for inclusion during the packaging operation	• NLTP to furnish exact wording of labels by 3 May 2004 • NLTP to find funding for addition of these labels to the TB Patient Packs
Special packaging for the TB Patient Packs	• Shipping container must identify as being from the NLTP, whether Category I or III TB Patient Pack and other required information to be identified (page 46 par. 7 tender letter) • Shrink foil packing of each individual Patient Pack • Booklet to guide the health care worker how to use the TB Patient Packs must be packed loose inside shipping container • Shipping container must have a plastic bag inside to protect TB Patient Packs from the environment during transport and subsequent storage • Preferably only 1 standard size for shipping container for 10 TB patient packs to be used.	• Requirements discussed with the manufacturer for inclusion during the packaging operation Note: this is a requirement as per the tender letter: see under Technical specs 1.1 on page 44	• NLTP to furnish exact wording on the shipping containers by 3 May • NLTP to find funding for booklet printing and deliver to manufacturer by 15 May 2004 • NLTP will receive samples and eventual additional costing for 3 different outer cartons. (10, 20, 30 patient packs)

Decision to make	Results	Status of activity	Remaining activities and dates to complete
Cost of the TB Patient Pack	• Tender was let, supplier selected and contract signed	•	none
Decide on implementation scheme	•	•	•

Preparation phase (pre-implementation)

Preparation activity	Status of implementation	Remaining activity and dates to complete
Determine best way to use up existing stock of TB drugs to be phased out	• Obtained stock position of each drug currently in NLTP stores • Decision made to standardize regimens for nomadic and non-nomadic TB patients • Various scenarios are being studied to use up existing drugs	• Choose best scenario by week of 3 May 2004-04-29 • Determine which separate drugs must be purchased to assure that complete regimens are available during phase out of current drugs by week of 7th • Request MOH to procure additional drugs in next tender
Decide on shelf life trigger for collection for redistribution	• One year or less remaining shelf life and not likely to be used in clinic: warn supervisor to collect and re-distribute	• Include in NLTP manuals and training
Prepare list of Health Centres selected for introduction and use of Patient Packs	• In consultation with PTLCs (& some DTLCs)	• Before May 10th
Add Patient packs to NLTP inventory and ordering stationary		• Print in next Edition
Add patient pack instruction in NLTP guidelines		• Print in next edition
Obtain list of district stores and health centres where additional shelving or cupboards are needed to store the Patient Packs	• Funding is promised • Meeting with DTLCs to discuss which facilities will need shelving or cupboards • Starting to collect data on cost for upgrades	
Organise training for all health staff involved	• Prepare training material for end users • Prepare training material / topics for DTLCs & PTLCs • Test training materials • Train and instruct PTLCs on Patient pack use, • PTLCs to train and instruct DTLCs • DTLCs to train and instruct HC	• Before May 21st • Before May 21st • Before end of May • 1st week of June (1-4) • 2nd week of June (7-11) • June 14 - 30

Preparation activity	Status of implementation	Remaining activity and dates to complete
	staff involved	
Set training timetable and secure funding	• Decide on dates and No. of participants per target group • Prepare budget, seek funding	• Before May 15
Check if registration of Patient Packs/contents is required.	• In co-operation with DELIVERI, KEMSA and manufacturer: check with Kenyan Pharmacy & Poisons Board	
Final decision on storage location(s) after delivery by manufacturer	• Total order stored at KEMSA • Partial storage at KEMSA Provincial Stores (additional hired stores) • Prepare logistics and distribution plan for same	• To be done by JSI and KEMSA, • Follow up by C.U.
Set implementation calendar with all stakeholders	• Date delivery of total No. of Patient Packs at KEMSA Central and or other stores. • Set dates and quantities to be distributed to HCs • Inform responsible staff and prepare regional and district stores involved	• Patient packs not to arrive before HC staff has received training
Set up post- delivery Quality Control System for Patient Packs	• In close co-operation with KEMSA (buyer), Pharmacy & Poison Board (quality control agency of Kenya) and NLTP (user)	• Before 31st May • See separate annex
Develop a pre- delivery Quality Control System all NLTP pharmaceuticals	• In close co-operation with KEMSA (buyer), Pharmacy & Poison Board (quality control agency of Kenya) and NLTP (user)	• Before 30th June in order to be included in next tender
Develop monitoring criteria to evaluate if introduction and use was successful	• Could be done in co-operation with D.M. consultant of MSH • Monitoring • Could be used for presentation at D.M. workshop at next IUATLD meeting	• Preferably before patient packs arrive at H.C.s • Before end of August
Prepare product specifications for next tender of NLTP products	• As much as possible including all that was learned during above mentioned activities, but in time for next tender, and in co-operation with all players • Find out latest dates	• Next tender will be floated in July/August: Specs finalised before mid June?

Annex 2

Supervisory Checklist for Health Units
***TB Patient Packs* and Other Drugs**

District: _____ Date: _____/_____/_____

Health Unit: _____ ***Supervisor:*** _____

1. Storeroom for drugs and patient kits	**Yes**	**No**
Are all products arranged for easy access?		
Are all products and containers stored off the floor?		
Are the containers stored in a secure manner (prevents pilferage)?		
Is there sufficient space to store new deliveries?		
2. Patient treatment room	**Yes**	**No**
Are all patient packs and drugs arranged for easy access?		
Do the patient packs have the name of the patient, TB register number and patient's weight written on them?		
Do TB *register cards* show that TB drugs are being recorded when the patient takes them?		
Do *patient packs* show that drugs are being recorded as swallowed once the patient takes them?		
3. Inventory and Availability	**Yes**	**No**
Is the stores keeper aware of any drugs or patient packs that will expire before they can be used?		
Of patient packs received does the actual number in storage areas correspond with the quantity in the register books (BIN cards)?		
Are products with shortest expiration dates stored in front of others?		
Are the patient packs and other drug quantities needed for the next delivery period calculated correctly? (based on expected number of patients)		
Are there damaged or expired products sitting around?		
4. Partly used Patient Packs	**Yes**	**No**
Are the excess drugs from patient packs stored in separate containers for each type of drug? (excess drugs happen when the patient is of lighter weight, transfers, stops coming to the health center or dies)		
Are you picking up the excess drugs from patient packs and carrying with you? Write the drug names, strength, expiry dates, and quantities on the next page		

List of Excess Drugs Removed from Health Units

District: _____ Date: _____/_____/_____

Health Unit: **_____** ***Supervisor:*** **_____**

Note: please list all batch numbers and expiration dates of the same drug

Name of drug	Strength of drug	Expiry dates	Quantities
RHZE	**150/75/400/275 mg**		
RHZ	**120/50/300 mg**		
EH	**400/150 mg**		
RH	**150/100 mg**		
E	**400 mg**		
S	**1 gm**		
S	**750 mg**		

Annex 3

Supervisory Checklist for District Stores
***TB Patient Packs* and Other Drugs**

District: _____ Date: _____/_____/_____

***Supervisor:* _____**

1. Storage area for drugs and patient kits	**Yes**	**No**
Are all products arranged for easy access?		
Are all products and containers stored off the floor?		
Are the containers stored in a secure manner (prevents pilferage)?		
Is there sufficient space to store new deliveries?		
2. Inventory and Availability	**Yes**	**No**
Are products with shortest expiration dates stored in front of others?		
Are there damaged or expired products sitting around?		
Is the store keeper aware of any drugs or patient packs that will expire before they can be used?		
Are drug register books (BIN cards) up-to-date showing all receipts from provincial stores and issues to health units of TB Patient Packs and other drugs?		
Does the physical count of patient packs and other drugs equal the quantities written on the drug register books (BIN cards)?		
According to the drugs register (BIN cards) have there been stock-outs of TB Patient Packs or other drugs at this facility?		
Is there documentation showing the average quantities needed of each product including TB Patient Packs?		
Is there a formula or method to calculate periodic needs?		
Is there a list of already expired products?		
Is there a list of drugs that will expire before they are used?		
3. Partly used Patient Packs	**Yes**	**No**
Are the excess drugs from TB Patient Packs stored in separate containers for each type of drug? (excess drugs happen when the patient is of lighter weight, transfers, stops coming to the health center or dies)		
Are the excess drugs being delivered to provincial stores on a quarterly basis for re-packing? Are the Supervisor Checklists from Health Units accompanying the excess drugs from TB Patient Packs?		

List of Excess Drugs Removed from Health Units

District: _____ Date: _____/_____/_____

Supervisor: _____

Note: please list all batch numbers and expiration dates of the same drug

Name of drug	Strength of drug	Expiry dates	Quantities
RHZE	**150/75/400/275 mg**		
RHZ	**120/50/300 mg**		
EH	**400/150 mg**		
RH	**150/100 mg**		
E	**400 mg**		
S	**1 gm**		
S	**750 mg**		

Annex 4

Repacking Procedure for TB Patient Packs

Every month the district supervisor will pick up all Patient Packs from health centers that are no longer being used for a patient. For example, Patient Packs that are no longer used happen when a TB patient transfers to another health center for treatment, stops coming to the health centre or dies. Since drugs are costly and the MOH provides TB treatment free of charge, it is in the best interest of everyone to repack unused drugs into new Patient Packs.

Every quarter the district supervisor will carry all partially-used Patient Packs from their districts to the KEMSA provincial stores where re-packing will take place.

> *Note: Partially used Patient Packs should be picked up as quickly as possible since the RHZE product inside the Patient Pack has only a 2 year expiry date.*

Set up line for unpacking and repacking

- Set up a packing line using tables or other suitable furniture
- Have the quality inspector verify that no materials from previous unpacking or repacking operations have been removed before starting a new repacking operation

Unpacking the partially used Patient Packs

- Gather all Patient Packs and group into Category I and Category III at the head of the packing line
- Obtain two empty boxes, one for each of the drugs to be *unpacked* so as not to mix the drugs in the same container
- Open each partially used Patient Pack received from the districts, remove the contents and place in one of the empty boxes—only place one product per box so as not to mix products. Contents of the Patient Packs consist of inner boxes and blisters
- Continue this procedure until all partially used Patient Packs have been unpacked

Packing the new Patient Packs for Category I

Repack Category I Patient Packs first before proceeding to repack Category III packs

- Make sure the repacking line is clear of all materials except those for repacking Category I Patient Packs
- Obtain a copy of the form: *Record of Re-packing Patient Packs for **Category I*** to control the repacking operation
- Take a Patient Pack *empty* container for Category I (RHZE and EH) and stick on two labels as follows:
  - a new preprinted label over the original label containing information about the patient's name, weight and registration number
  - a new preprinted label over the other end of the Patient Pack with the following information:
    - Prepacked by GOK-MOH-NLTP on _____(date)

  - Patient Pack number _____
- For the Patient Pack container you just labeled prepare two inner containers as follows:
  1. Take an unpacked inner *empty* container labeled to contain RHZE and place inside 24 blisters of 10 tablets of RHZE
     - Examine all 24 blisters and choose the shortest expiration data (will expire soonest)
     - Using a permanent ink marker, change the expiration date on the RHZE container to the shortest expiration date
  2. Take an unpacked inner *empty* container labeled to contain EH and place inside 36 blisters of 10 tablets of EH
     - Examine all 36 blisters and choose the shortest expiration data (will expire soonest)
     - Using a permanent ink marker, change the expiration date on the EH container to the shortest expiration date
- Place the two inner containers of RHZE and EH into the newly labeled Patient Pack outer container for Category I patients
- For each new pack that is re-packaged, write the following information on the form *Record of Re-packing Patient Packs for Category I*:
  - Heading information
  - Each drug name and strength placed into the new pack (for example: EH 400/150 mg)
  - Name of manufacturer of each drug
  - Expiration dates for each drug
  - For each drug name, the manufacturer's batch or lot number
  - Quantity placed inside the new Patient Pack for each drug

  Note: the NLTP will decide if Patient Pack inner and outer containers will be reused for repacking purposes, otherwise new containers of the same dimensions may be provided in which case you may not need to place the labels as indicated above

Packing the new Patient Packs for Category III

- Make sure the repacking line is clear of all materials except those for repacking Category III Patient Packs
- Obtain a copy of the form *Record of Re-packing Patient Packs for* ***Category III*** to control the repacking operation
- Take all Patient Pack empty outer containers and stick on two labels as follows:
  - a new preprinted label over the original label containing information about the patient's name, weight and reference number
  - a new preprinted label over the other end of the Patient Pack with the following information:
    - Prepacked by GOK-MOH-NLTP on _____(date)
    - Patient Pack Number _____
- For the Patient Pack outer-container you just labeled prepare two inner-containers as follows:

2. Use an unpacked inner *empty* container labeled to contain RHZ and place inside 24 blisters of 10 tablets of RHZ
   - Examine all 24 blisters and choose the shortest expiration data (will expire soonest)
   - Using a permanent ink marker, change the expiration date on the RHZ container to the shortest expiration date
3. Use an unpacked inner empty container labeled to contain EH and place inside 36 blisters of 10 tablets of EH
   - Examine all 36 blisters and choose the shortest expiration data (will expire soonest)
   - Using a permanent ink marker, change the expiration date on the EH container to the shortest expiration date

- Place the two inner containers of RHZ and EH into the newly labeled Patient Pack outer container
- For each new pack that is re-packaged, write the following information on the form *Record of Re-packing Patient Packs for Category III*:
  - Each drug name and strength placed into the new Patient Pack (for example: EH 400/150 mg)
  - Name of manufacturer of each drug
  - For each drug name, the expiry dates
  - For each drug name, the manufacturer's batch or lot number
  - For each drug name, the quantity placed inside the new Patient Pack

  Note: the NLTP will decide if Patient Pack inner and outer containers will be reused for repacking purposes, otherwise new containers of the same dimensions may be provided in which case you may not need to place the labels as indicated above

Quality control

- There should be a minimum of two people carrying out the re-packing operation
- The second person could serve as the quality inspector since a second person must verify the following information recorded on the form *Record of Re-packing Patient Packs for Category III:*
  - Drugs and strengths are correct
  - Quantities are correct
  - Expiry dates are correct
  - Names of manufacturers are correct
  - Manufacturer's batch or lot numbers are correct

Finishing the re-packing operation

- When there are no longer enough drug blisters to fully pack another Patient Pack stop the repacking operation
- Take the few drugs left over and dispose of them according to the procedures established by the MOH
- Take any unused inner or outer Patient Pack containers and store for future repacking operations (unless the NLTP decides to only use new containers)

Clearing the repacking line

- Before any repacking operation begins, the quality inspector must observe that the repacking line has been completely cleared of materials from the previous repacking operation
- Quality control inspector will then sign that the line has been cleared at the top of the forms *Record of Re-packing Patient Packs* and is ready to be used for repacking

Retaining the forms "Record of Re-packing Patient Packs"

- Retain all the forms *Record of Re-packing Patient Packs for Category I* and *Record of Re-packing Patient Packs for Category III* in a safe place
- Establish an electronic spreadsheet to enter the information from the forms. This allows sorting and location of specific repacked goods according to batch number of expiry date. Each form entered should have a special code for resorting that consists of the date, form number and repacking center. For example: 405041A would mean 4 May 2004, form 1, of repacking center A.
- You may need to refer to these forms in the future to discount any discrepancy found in one of the repacked Patient Packs or if there is another quality complaint from the districts

Record of Re-packing Patient Packs for Category I:

Date re-packing operation is carried out: _____
Persons working on repacking line: _____
Persons conducting quality control inspections: _____ Line cleared of all previous materials _____

Patient Pack number	Names and strengths of drugs added to new Patient Pack	Expiry date of each drug added	Name of manufacturer of each drug added	Manufacturer's batch or lot number of each drug added	Quantity of each drug added	Initials of person repacking	Initials of quality inspector
1	RHZE (150/75/400/275 mg)						
	EH (400/150 mg)						
2	RHZE (150/75/400/275 mg)						
	EH (400/150 mg)						
3	RHZE (150/75/400/275 mg)						
	EH (400/150 mg)						
4	RHZE (150/75/400/275 mg)						
	EH (400/150 mg)						

Record of Re-packing Patient Packs for Category III

Date re-packing operation is carried out: _____
Persons working on repacking line: _____
Persons conducting quality control inspections: _____ Line cleared of all previous materials _____

Patient Pack number	Names and strengths of drugs added to new Patient Pack	Expiry date of each drug added	Name of manufacturer of each drug added	Manufacturer's batch or lot number of each drug added	Quantity of each drug added	Initials of person repacking	Initials of quality inspector
1	RHZ (120/50/300 mg)						
	EH (400/150 mg)						
2	RHZ (120/50/300 mg)						
	EH (400/150 mg)						
3	RHZ (120/50/300 mg)						
	EH (400/150 mg)						
4	RHZ (120/50/300 mg)						
	EH (400/150 mg)						

Annex 5

Scenarios for Phase in of Patient Packs

Phase in Scenarios if continue with current regimens

Number of patients (120,000**)**	**scenario 1** Nomadic=12200 (4880sm+;854 retreat;5367sm-ep) Children=10992 Non-nomadic=99905 (43919 sm+, 7685 retreat,48300 sm-ep	**scenario 2** Nomadic=12200 (4880sm+;854 retreat;5367sm-ep) Children=10992 Non-nomadic=99905 (43919 sm+, 7685 retreat,48300 sm-ep (give 9030 patient pack and 39270 loose tabs)

Drugs	Exp. Dates	Quantities	Remaining (scenario 1)	Remaining (scenario 2)
RHZ (120...)+RH (150..)	Sept 2005,Nov 2005 + GDF	14,358,744	-2,438,226	-126
EH (400/150)	Apr 2006-Feb 2008	17,591,000	-35,495,140	15,102,500
RHZE(150/75/400/275)	GDF--arrival 9/04	6,777,264	-8,111,016	2,429,544
E`400	Jan 2006 + GDF--arrival 9/04	4,307,360	2,001,860	2,001,860
RH 150/75	Apr 2006 + GDF--arrival 9/04	8,589,780	2,000,220	2,000,220
S1 g	12/1/2006 (1500 vials 750 mg)	933,572	421,232	421,232
Patient Pack Category I	Cosmos arrival June 04	60,000	60,000	16,081
Patient Pack Category III	Cosmos arrival June 04	40,000	40,000	30,970

Assumptions for scenario 1: shows consumption figures for one full year; no Patient Packs are used; no adjustments for defaulters is made

Results for scenario 1: use all RHZ during year but must purchase 2,438,226 tabs.of RHZ, 35,495,140 tabs.or EH and 6,111,016 tabs of RHZE

Assumptions for scenario 2: shows consumption figures for one full year: some Patient Packs are used; no adjustment for defaulters is made

Results for scenario 2: use all RHZ in one year, no need to purchase any additional drugs but have high balance of EH (due to use of 43919 Cat I Patient Packs

Phase in Scenarios if regimens for nomadic and nomadic are standardized

	scenario 1
Number of patients (121,998)	48,799 (Sm+) (33370 get Patient Packs, 15429 get loose drugs) 8,540 (Sm-) 53677 (Sm-EP) (4160 get Patient Packs; 49517 get separate drugs) 10,992 (Children)

Drugs	**Exp. Dates**	**Quantities**	**Remaining (scenario 1)**
RHZ (120...)+RH (150..)	Sept 2005,Nov 2005 + GDF	14,358,744	-126
EH (400/150)	Apr 2006-Feb 2008	17,591,000	-5,789,560
RHZE(150/75/400/275)	GDF--arrival 9/04	6,777,264	-96
E`400	Jan 2006 + GDF--arrival 9/04	4,307,360	1,745,360
RH 150/75	Apr 2006 + GDF--arrival 9/04	8,589,780	1,487,220
S1 g	12/1/2006 (1500 vials 750 mg)	933,572	421,172
Patient Pack Category I	Cosmos arrival June 04	60,000	26,630
Patient Pack Category III	Cosmos arrival June 04	40,000	35,840

Assumptions for scenario 1: treatment regimen same for nomads and non-nomads; some patient packs consumed; 15% default rate for 92219 patients

Results for scenario 1: consumption of all RHZ during year; no drugs will expire; EH will run out midyear but 15% expected default rate will free up 4979826 tablets; can increase use of Patient Packs at that time

Annex 6

Quantification of Drug Needs for 2005 - 2006

Number of patients
Cat.I - 57094
Cat. II - 9991
Cat. III > 15 yr - 62790
Cat. III < 15 yr - 12860
(Total patients: 142,735)

Drugs	Exp. Dates	Quantities end of year	Quantities to order for 2005-2006
RHZ (120...)+RH (150..)		-126	0
EH (400/150)		-809,734	0
RHZE(150/75/400/275)		-96	3,596,664
E`400	Jan-06	1,745,360	1,251,940
RH 150/75	Apr-06	1,487,220	6,822,180
S1 g	Dec-06	421,172	178,288
Patient Pack Category I	Apr-06	26,630	28,264
Patient Pack Category III	Apr-06	35,840	26,950

(added 2,200 Patient Pack for Category I for probable need when EH runs out in 2004-05)

Annex 7

Proposed Quality Control actions for delivery of the first shipment of TB Patient Packs from Cosmos as per 30th June 2004.

In view of lateness of setting up a Quality Assurance system: after contract has been signed and products have already been produced, a POST-delivery Quality Control system can be introduced for this contract.

A PRE-delivery Q.C. system is to be developed so as to be included in next tender letter and contract.

Please note that Q.A. and Q.C are the joint responsibility of the buyer (KEMSA), the user (NLTP), and the Drug Regulatory Authority (Pharmacy and Poisons Board of Kenya).

Therefore a Q.A. and Q.C. system should be developed **in conjunction by all parties** and **approved by all concerned authorities** as to ensure a legal basis for the quality control activities and possible follow-up actions.

For **this shipment** the Q.C. system should at least comprise:

- Check that all deliveries conform with specifications in the tender, contract and packing lists: Outer packing, labeling instructions on inner packing, literature, color of tablets, etc
- Check remaining shelf life (5/6 of total) upon delivery (per. 2.1 page 45 tender letter)

Request at least the following documentation:

- WHO type Batch Analysis Certificate for each batch delivered
    - A qualified pharmacist to check if all test data are within specifications as per relevant Pharmacopoeia.

- A sample taking system for control laboratory tests to be developed:
    - For this order one random sample of sufficient size (i.e. one full patient pack) out of every 5 batches could be taken. Sample taking to be done, documented and signed by at least 2 designated persons.
    - Physical check of product, color, smell, firmness, "do-it-yourself" dissolution test
    - If a Thin Layer Chromatography (TLC) mini-lab were available these samples could be tested for sufficient active pharmaceutical ingredient (API)
    - If TLC test is out of specs, submit a sample to competent and independent laboratory for control testing
    - Possible action to be taken when out of specs to be laid down in a Standard Operation Procedure

For next orders:

A pre- delivery Quality Control system to be developed, documented and approved by all parties concerned and included in the next tender letter!